UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,455	04/05/2006	Moise Azria	PA/4-33288A	9884

1095 7590 02/20/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
XIE, XIAOZHEN	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
02/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,455	AZRIA ET AL.	
	Examiner	Art Unit	
	XIAOZHEN XIE	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,9,10 and 17-19* is/are pending in the application.

4a) Of the above claim(s) *17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081203*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *MayoClinic Web page*.

DETAILED ACTION

Response to Amendment

The Information Disclosure Statements (IDS) filed 3 December 2008 has been entered. Applicant's amendments of the specification and the claim filed 3 December 2008 have been entered.

Claims 3-4, 7-8, 11-16 and 20-23 are cancelled. Claims 1-2, 5-6, 9-10 and 17-19 are pending. Claims 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 1-2, 5-6 and 9-10 are under examination.

Specification

It is noted that Applicant has amended the specification as suggested in 37 CFR 1.77(b) to include lettered section heading.

Claim Objections/Rejections Withdrawn

The objection to claims 8 and 9 for using acronyms without setting out the full names of the terms at the first use is withdrawn in response to Applicant's amendment of the claims.

The objection to claim 21 for typographical error is withdrawn in response to Applicant's cancellation of the claim.

The rejection of claims 1-10, 21 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in response to Applicant's amendment of the claims.

The rejection of claims 1-4 and 6-10 under 35 U.S.C. 102(b) as being anticipated by Bay et al. (US 20020065255 A1), is withdrawn in response to Applicant's amendment of the claims to limit the patient population.

The rejection of claims 1-7, 10, 21 and 23 under 35 U.S.C. 102(b) as being anticipated by Ghirri et al. (US 6,352,974 B1), is withdrawn in response to Applicant's amendment of the independent claim1 to recite the specific delivery agent in the composition.

Claim Rejection Maintained

Double Patenting

Claim 2 remains provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9 and 10 of copending Application No. 11/577,127.

Claims 1-2 and 10 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 12/132,642.

Claims 1-2 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 28 and 29 of

copending Application No. 12/093,383, in view of Ghirri et al. (US 6,352,974 B1, Date of Patent: 5 March 2002).

Applicant argues that the present application is further along in prosecution than the above-identified co-pending applications. Applicant requests that upon allowance of the claims under consideration in this application, the double patenting rejection in this application will be withdrawn, and a provisional double patenting rejection will be made in the above-identified co-pending applications, which may then be converted into a double patenting rejection upon the present application issuing into a patent.

The instant claims, however, are not in condition for allowance (see the following). Therefore, the provisional obviousness-type double patenting rejections are maintained.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 5-6 and 9-10 are rejected under 35 U.S.C. 103(a), as being unpatentable over Ghirri et al. (US 6,352,974 B1, Date of Patent: 5 March 2002), in view of Bay et al. (US 20020065255 A1, Pub. Date: 30 May 2002).

The instant claims are directed to a method of treating osteoarthritis in a patient in need thereof, or a method of inhibiting resorption and/or normalizing turnover of subchondral bone in a patient having osteoarthritis or osteoporosis, or in a postmenopausal woman, comprising orally administering to said patient a pharmaceutical composition comprising between 0.4 and 2.5 mg of salmon calcitonin in free or salt form and a delivery agent selected from the group of 5-CNAC, SNAD, SNAC and disodium salts thereof (claims 1, 2); wherein the salmon calcitonin is conjugated to a polymer molecule (claim 5); wherein the pharmaceutical composition further comprises at least one pharmaceutically acceptable pH-lowering agent, at least one absorption enhancer, and an enteric coating (claim 6); whereas said delivery agent is disodium salt thereof (claim 9); and whereas the pharmaceutical composition comprises a delivery agent in micronized form (claim 10).

Ghirri et al. teach oral pharmaceutical compositions comprising calcitonin or a conjugate thereof (see claims). Ghirri et al. teach that calcitonins are used to treat a variety of conditions, e.g., Paget's disease (the symptoms of Paget's disease include osteoarthritis, see for example the attached MayoClinic webpage regarding the disease), post-menopausal osteoporosis (col. 2, lines 31-35). Ghirri et al. teach that the preferred calcitonin is salmon calcitonin, or a synthetic salmon calcitonin (col. 5, lines 14-24), and that the calcitonin may be conjugated to a polymer, e.g., to a polyalkylene glycol moiety (col. 5, lines 25-28). Ghirri et al. teach that the oral calcitonin pharmaceutical compositions may be milled and/or sieved to provide a particulate solid, e. g., granules or a powder (col. 5, lines 42-47). Ghirri et al. teach that the composition

should be enteric coated to prevent gastric degradation (col. 6, lines 5-7). Ghirri et al. also teach other additives that can be included in the compositions, for example, adding phosphoric acid to adjust the pH to 4 (col. 10, Example 2), and adding absorption enhancers to the compositions (Example 6). Ghirri et al. teach that the compositions preferably have a unit dose of active material from about 20 IU to about 600 IU (col. 6, lines 21-26); for salmon calcitonin, each mg has up to, i.e., less than, 6500 IU activity (col. 3, lines 38-40). Therefore, the unit dose of salmon calcitonin in Ghirri et al.'s composition meets the instant limitation of "between 0.4 and 2.5 mg of a calcitonin".

Ghirri et al. teach as set forth above. Ghirri et al., however, do not teach that the oral calcitonin pharmaceutical composition comprising a delivery agent selected from the group of 5-CNAC, SNAD, SNAC, and said delivery agent is disodium salt thereof.

Bay et al. teach pharmaceutical compositions comprising a delivery agent, which is a disodium salt of 5-CNAC, SNAD, or SNAC, and an active agent, such as salmon calcitonin [0010] [0015] [0035]. Bay et al. teach that the pharmaceutical compositions may be formulated into an oral dosage unit form, e.g., particles, powders or sachets [0015] [0042]. Bay et al. teach that the disodium salt of 5-CNAC, SNAD, or SNAC has greater efficacy for delivering the active agent than the corresponding monosodium salt and free acid [0009].

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ghirri et al., with those of Bay et al., to add a disodium salt of 5-CNAC, SNAD, or SNAC into the oral calcitonin pharmaceutical composition. One of ordinary skill in the art would have been motivated

to do so, because Bay et al. teach that the disodium salt of 5-CNAC, SNAD, or SNAC can increase efficacy for delivering the active agent, such as salmon calcitonin in an oral pharmaceutical composition. Therefore, the combined teachings provide a reasonable expectation of successfully delivering the salmon calcitonin for therapeutic treatment.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
January 30, 2009

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646